UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,020	06/23/2004	Yutaka Ashida	AIA-107-PCT	2767

28892 7590 01/12/2006

SNIDER & ASSOCIATES
P. O. BOX 27613
WASHINGTON, DC 20038-7613

EXAMINER	
CLARK, AMY LYNN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,020	ASHIDA ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *4-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/19/05, 11/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the election by Applicant of Group I, Claims 1-3 and 17, without traverse on December 9, 2005.

Claims 13 and 24-53 are withdrawn, without traverse, from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

Currently, Claims 1-3 and 17 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Longley (A), in view of Zsebo et al. (B).

Applicant claims a screening method for active ingredients which exhibit effects of ameliorating pruritus, rough skin or sensitive skin, or effects of skin whitening, by inhibiting production and/or release of stem cell factor, the method being characterized by comprising the steps of contacting stem cell factor-expressing cells with test ingredients, assaying the amount of stem cell factor produced and/or released by said cells and selecting test ingredients which reduce the amount of production and/or release of stem cell factor as said active ingredients, wherein said SCF-expressing cells are subjected to stimulation to promote stem cell factor production and/or release, as Claim 1. Applicant further claims a screening method according to claim 1, wherein said stimulation is drying stimulation to promote stem cell factor production and/or release, as Claim 2. Applicant further claims a screening method according to claim 1, wherein said stem cell factor-expressing cells are contacted with said test ingredients, after which said cells are subjected to stimulation and then the amount of stem cell factor produced and/or released by said cell is assayed to select said active ingredients, as Claim 3. Applicant claims the screening method of claim 2, wherein said stem cell factor-expressing cells are contacted with said test ingredients, after which said cells are subjected to stimulation and then the amount of stem cell factor produced and/or released by said cells is assayed to select said active ingredients, as Claim 17.

Longley teaches a method of identifying a composition, a compound or a procedure which can produce a skin response in a subject comprising administering the

composition or compound or applying said procedure to hyperpigmented transgenic mice which express endogenous epidermal stem cell factor (SCF) and analyzing the contacted skin for a response (See abstract and column 4, lines 48-54). Longley further teaches a method of identifying a compound which potentially treats a skin response in a mammal's (which can be either a mouse or human- See column 15, Claim 8) skin, which comprises inducing a skin response in a transgenic mouse's skin which expresses endogenous epidermal stem cell factor with an irritant or an allergic dermatitis inducing agent (See column 16, Claim 10), analyzing the contacted skin for a response (See abstract and column 4, lines 48-54 and column 14, Claim 1, introduction and part a), administering to the transgenic mouse or a human the compound, which can be an epidermal stem cell factor inhibitor (See column 16, Claim 17), in an amount effective to treat the skin response and determine whether the skin response indicates that the compound potentially treats the skin response in the mammal's skin (See column 15, Claim 1, part b), please note that this reads on chemical stimulation and drying stimulation. Longley further teaches a method of identifying a composition, a compound or a procedure which can reduce radiation damage to the skin of a subject (See abstract and column 15, Claim 5). Longley further teaches the radiation damage can be caused by ultraviolet light and that the radiation damage is tanning, carcinogenesis, photo-aging, photodamage or the development of melanoma (See column 15, Claims 6 and 7), please note that this reads on ultraviolate radiation and irradiation stimulation. Longley further teaches providing a pharmaceutical composition for treating human skin conditions comprising a compound that can treat skin disease of

transgenic mice, which express endogenous epidermal stem cell factors and a suitable carrier, wherein the compound specifically targets the epidermal stem cell factor or its receptor (See column 2, lines 34-39). Longley further teaches that blocking stem cell factor by administration of ACK2 decreased the magnitude of ear swelling in transgenic mice and averaging over time, there is a difference between ACK2 treated and the control saline treated transgenic mice (See column 10, lines 33-42). Longley further teaches an effective amount of active ingredients was determined to inhibit the interaction between stem cell factor and its receptor, as was followed clinically in Longley's studies clearly shown in the "experimental details" section column 8, lines 49-67 and continued through to column 10, line 51, which was determined by monitoring the activity of stem cell factor. Longley further teaches administering a composition or compound to the irritated skin of a mouse and analyzing the skin response, wherein reduction of skin response indicates that the composition, compound or procedure can reduce skin response (See column 2, lines 7-24).

Zsebo teaches pharmaceutical compositions, including stem cell factor (SCF) and antibodies specifically binding stem cell factor (See column 4, lines 26-28), for treating disorders (See abstract). Zsebo further teaches a method to quantify stem cell factor in human serum samples involving radioimminoassay procedures, whereby an stem cell factor preparation is incubated together with antiserum and antibody bound .sup.125 I-SCF, which is subsequently added. Zsebo further teaches that the percent inhibition of .sup.125 I-SCF binding produced by the unlabeled standard is dose dependent (See Example 7). Zsebo further teaches that stem cell factors have the

ability to stimulate growth of primitive progenitors including early hematopoietic progenitor cells are and are also able to stimulate non-hematopoietic stem cells such as neural stem cells and primordial germ stem cells (See column 3, lines 62-67).

The teachings of Longley and Zsebo are set forth above. Longley does not expressly teach a method to quantify stem cell factor and the use of the quantification as a way of assaying the effect of a compound on pruritus, rough skin or sensitive skin, or effects of skin whitening nor does Longley expressly teach the method steps in the order as claimed of inhibiting production and/or release of stem cell factor, the method being characterized by comprising the steps of contacting stem cell factor-expressing cells with test ingredients, assaying the amount of stem cell factor produced and/or released by said cells and selecting test ingredients which reduce the amount of production and/or release of stem cell factor as said active ingredients, wherein said SCF-expressing cells are subjected to stimulation to promote stem cell factor production and/or release in this order. However, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to employ the method taught by Zsebo to determine the amount of production and/or release of stem cell factor to provide the instantly claimed invention because at the time the invention was made, measuring the level of stem cell factor affected by a compound is a good measurement of the affect of a compound on treating a disorder, where decreased SCF is desired, was well known in the art, as taught by Zsebo, as was the importance of providing a pharmaceutical composition for treating human skin conditions comprising a compound that can treat

skin disease, wherein the compound specifically targets the epidermal stem cell factor or its receptor, as clearly taught by Longley.

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Regarding the specific order of the method steps in claim e, it would have been obvious to practice the method steps made obvious by the combined teaching of the cited reference in either order because Longley teaches the method as comprising those steps and one of ordinary skill in the art would have practiced those steps in either order. One of ordinary skill in the art would be able to determine that changing the order of the method steps could potentially lead to different compounds, however, the effect of the compound on treating skin disease, wherein the compound specifically targets the epidermal stem cell factor or its receptor, is the same.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may

be referred to the Electronic Business Center (EBC) at

http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood.

MICHELE FLOOD
PRIMARY EXAMINER

Amy L. Clark
AU 1655

Amy L. Clark
January 5, 2006